GOVERNMENT OF INDIA
AYURVEDA,YOGA & NATUROPATHY,UNANI,SIDDHA AND HOMEOPATHY (AYUSH)
LOK SABHA

UNSTARRED QUESTION NO:4524
ANSWERED ON:12.08.2016
Clinical Trials of Traditional Medicines
Butta Smt. Renuka;Rori Shri Charanjeet Singh

Will the Minister of AYURVEDA,YOGA & NATUROPATHY,UNANI,SIDDHA AND HOMEOPATHY (AYUSH) be pleased to state:

Will the Minister of AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH) be pleased to state:

(a) whether the Government has permitted clinical trials of traditional medicines and if so, the details thereof;

(b) whether the Government proposes to revise the guidelines on clinical trials for new AYUSH drugs including Ayurveda and if so, the details thereof; and

c) the time by which the revised guidelines on clinical trials for new AYUSH drugs are likely to be implemented?

Answer

ANSWER
THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYURVEDA,
YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY
(SHRI SHRIPAD YESSO NAIK)
(a): Drugs & Cosmetics Act, 1940 and Rules thereunder do not have any provisions for clinical trials on traditional medicines. However, on receipt of clinical trial proposals on Ayurvedic and herbal medicines, the then Department of AYUSH granted permission to ten institutes for conducting clinical trials during the period April, 2008 to September, 2010. The details of these clinical trials are annexed.
(b) & (c): New AYUSH drugs including Ayurveda are not defined in the provisions of the Drugs & Cosmetics Act, 1940 and Rules thereunder. The Government published "Good Clinical Practice Guidelines for Clinical Trials in Ayurveda, Siddha and Unani Medicine (GCP-ASU)" in the year 2013 with the objective that the studies are scientifically and ethically sound and the clinical properties of the ASU medicines under investigation are properly documented. The guidelines do not have any legal binding to conduct the clinical trials and no proposal is under consideration to revise them.
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